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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,760

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1613

MAIL DATE

DELIVERY MODE

03/25/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,760	<b>Applicant(s)</b> DELUCA ET AL.	
	<b>Examiner</b> BLESSING FUBARA	<b>Art Unit</b> 1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-15 is/are pending in the application.
- 4a) Of the above claim(s) 3-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. The examiner acknowledges receipt of request for extension of time, amendment and remarks filed 01/13/2011. Claim 1 is amended. Claim 2 is canceled. Claims 1 and 3-15 are pending.

2. The amendment to claim 1 necessitates the rejections below.

### **Response to Arguments**

3. Previous rejections that are not reiterated herein are withdrawn; the rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Woo et al. ("Preparation Na Characterization of a Composite PLGA and Poly(Acryloyl Hydroxyethyl Starch) Microsphere System for protein Delivery," in Pharmaceutical Research, Vo. 18, No. 11, November, 2001) is withdrawn in view of the amendment to claim 1.

### **Claim Rejections - 35 USC § 103**

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Woo et al.

("Preparation Na Characterization of a Composite PLGA and Poly(Acryloyl Hydroxyethyl Starch) Microsphere System for protein Delivery," in Pharmaceutical Research, Vo. 18, No. 11, November, 2001) in view of Filvaroff et al. (US 20020058614).

7. Woo teaches a composite microsphere comprising PLGA, poly(Acryloyl Hydroxyethyl Starch) (ACHES) and proteins such as bovine serum albumin and horseradish peroxidase (see the whole document). The molecular weight of bovine serum albumin is known at 66,382 Da and that for Horseradish peroxidase is known at 40,000 Da and these molecular weights anticipate the molecular weight range of 200 to about 160,000 Da.

8. Woo teaches that the composite microsphere comprising PLGA and poly(Acryloyl Hydroxyethyl Starch) (ACHES) for delivery of proteins such as bovine serum albumin and Horseradish (66,832 Da for BSA and 40,000 Da for Horseradish). Woo does not use the composite microsphere with the peptides and proteins now claimed in claim 1 by amendment in which the limitation of canceled claim 2 is moved into claim 1.

9. However, it is known that PLGA microspheres have been used as carriers from insulin (see para. [0199], [0414], [0430], [0438], [0439] and [0451] of Filvaroff).

10. Therefore, since PLGA microspheres are known for carrying insulin, one having ordinary skill in the art at the time the invention was made would have expected that the composite microsphere of Woo comprising PLGA and polyacryloyl hydroxyethyl starch would be effective in carrying and delivering insulin because PLGA has been effective for the delivery of insulin.

### **Response to Arguments**

11. Applicant's arguments filed 01/13/2011 have been fully considered but they are not persuasive.

12. Applicant argues that Woo merely attempts to prepare composite microspheres for delivery for bovine serum albumin and horseradish peroxidase and that Woo “does not provide any teaching on how to prepare microspheres containing any other active ingredient” or also does not disclose if the composition comprising microspheres containing other active ingredients could be successful as delivery device; applicant went on to say that insulin is not readily soluble in aqueous buffer and the instant specification employed a 30% acetic acid to prepare the insulin solution as shown in Example 3, page 21 of the instant specification; applicant also argues that Filvaroff does not remedy the deficiencies of Woo because microsphere of Filvaroff is structurally different from the composite microsphere of Woo by disclosing that the microspheres are formed by microencapsulation of active ingredient in PLGA matrix; the result of this difference in applicant's opinion is that one of skill in the art would not expect the microsphere to work in the same way as the composite microsphere.

13. Response: The examiner agrees with applicant that while Woo discloses using composite microsphere to deliver proteins such as BSA and Horseradish peroxidase, Woo does not teach using the composite to deliver peptides such as insulin and that is the reason for rejecting claim 1 under 35 USC 103(a). Woo discloses composite microsphere just as claim 1. The reliance on Filvaroff is on the teaching that PLGA microspheres are known for carrying insulin and not on how the microsphere is formed. Also, instant claim 1 is not directed to processes of preparing microspheres or the preparation of insulin solution in 30% acetic acid; the claim is directed to

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composition. The microsphere of Woo comprises PLGA and is used to carry proteins such as BSA and Horseradish peroxidase so that it is reasonable for the skilled artisan to expect that the PLGA microsphere of Woo would also be capable of carrying peptides such as insulin since it is known in the art that PLGA microspheres are known for carrying insulin. Solubility of insulin in 30% acetic acid does not negate what is known in the art that PLGA microspheres carry insulin and solubility of insulin in 30% acetic acid is not a factual showing that the microspheres of Woo cannot be used to carry insulin, applicant has not also factually shown that the PLGA microsphere of Filvaroff does not and cannot carry insulin.

14. “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The argument presented by applicant does not take the place of factual showing.

15. Therefore, the examiner disagrees with applicant that the skilled artisan would not look to Filvaroff as a motivation to use the composite of Woo as carrier for peptides and other proteins. On the contrary, Filvaroff suggests and teaches the use of PLGA as carriers of peptides such as insulin with this suggestion and teaching providing the motivation to use the PLGA composite microsphere of Woo as carrier for insulin. The claimed composition is not patentable over the Woo teaching as modified by the guidance that PLGA microsphere carries insulin except factually shown otherwise that the PLGA composite microsphere of Woo cannot carry insulin.

16. No claim is allowed.

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17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

18. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Y. Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/  
Primary Examiner, Art Unit 1613